REMARKS

Applicant appreciates the examination of the present application as evidenced by the Office Action dated June 7, 2011 (hereinafter, "the Office Action"). Upon entry of this Amendment, Claims 1, 3, 6-10, 12, 3, 15, 16, 25, 28, 31-39 and 40-64 are pending in the present application.

In view of the foregoing amendments and following remarks to address the issues raised in the Office Action, reconsideration and withdrawal of the rejections to the present application are respectfully requested, and favorable action upon all pending claims is hereby requested.

I. Claim Rejections Under 35 U.S.C. §112

Claims 1, 3, 6-10, 12-13, 15-16, 25, 28 and 31-39 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *See* Office Action, page 2.

Applicant has amended the claims to incorporate the language in the Office Action recommended by the Examiner in order to address the concerns under §112, second paragraph. Accordingly, Applicant respectfully submits that this rejection has been overcome, and Applicant respectfully requests that this rejection be withdrawn.

II. Claim Rejections Under 35 U.S.C. §103

Claims 1, 3, 6-10, 12, 13, 15, 16, 25, 28 and 31-39 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gerba et al., "Endotoxin Removal by Charge-Modified Filters," *Applied and Environmental Microbiology*, Dec. 1985, p. 1375-1377 (hereinafter, "Gerba") in view of Brown et al., "The distribution of infectivity in blood components and plasma derivatives in experimental models of transmissible spongiform encephalophathy," *Transfusion*, Sept. 1998, p. 810-816 (hereinafter, "Brown"). *See*, Office Action, page 4. Specifically, the Examiner contends that "it would have been prima facie obvious to provide the methods of removal of infectious prions from plasma taught by Brown using Gerba's depth filter comprising cellulose and kieselguhr because Gerba teaches that his depth filter allows for enhanced removal of bacteria and bacterial endotoxin from solution." Office Action, page 5. However, Applicant respectfully disagrees and again submits that Gerba, alone or in combination with Brown, fails to render the pending claims obvious.

In view of the Examiner's suggestion, Applicant has amended the claims to clarify that the aqueous liquid contains a blood plasma product derived from plasma and that the abnormal infective prion proteins may be present in the blood plasma product or a plasma fraction thereby addressing the Examiner's concerns raised on page 8 of the Office Action. Thus, Applicant believes that the amendments further clarify and distinguish claims 1,3, 6-10, 12, 13, 15, 16, 25, 28 and 31-39.

However, to address further the Examiner's concerns, Applicant notes that the Examiner suggests that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified predictable potential solutions, a person of ordinary skill has good reason to pursue the known potential options...." Office Action, page 8. However, in the present case, it cannot truly be said that at the priority date of the present invention there were a "finite number of predictable potential solutions." In fact, since almost nothing was known about the chemical or physical structure of prion proteins, all the infinite panoply of separation methods available to the chemist of ordinary skill would have to be considered. This is **not** a "finite" number of options, but, in fact, an almost infinite number of options. Many separation processes are known in the field of chemistry ranging from chemical separation using chemical attraction and/or reaction to physical separation using temperature, pH, different solvents, etc. There is absolutely no reason to highlight filtration. However, if the ordinarily skilled artisan were to fortuitously decide that filtration might be a good option, why would the ordinarily skilled artisan decide that depth filtration using kieselguhr/perlite would be **the** way to proceed? The present invention is at least based upon the surprising discovery that a very specific type of filtration using a depth filter is uniquely capable of removing infective prion proteins, for example, as shown in Table 1. Other filters simply do not work in this capacity as we have discussed previously on the record. Where the present invention is at least based upon the discovery that a particular kind of filtration is uniquely successful in removing infective prion proteins, it seems highly unlikely that the ordinarily skilled artisan would turn to this very specific type of filtration process of all the known processes when searching for a technique to remove the relatively unknown prion proteins, which, as acknowledged by the Examiner, are indeed different, unrelated molecules from those discussed in Gerba.

In considering Brown, it is quite clear that Brown had no idea which portions of the blood plasma fractionation process might prove effective in removing infective prion proteins. Seemingly, the purpose of Brown was to discover the different levels of residual infective prion protein left by

different steps in the conventional blood plasma fractionation process in order to assess the risk of infective prion proteins being transmitted to humans by the blood plasma fractionation products. I 1998, Brown could have looked to the 1985 work of Gerba and concluded that depth filtration should be the method of removing prion proteins. However, it is clear that Brown had no idea regarding how, or even if, prion proteins could be removed from blood plasma products. Even at the end of the experimentation work that Brown reports, Brown does not propose that infective prion proteins could be removed by using any of the techniques employed in the conventional blood plasma fractionation process.

Further, considering the alleged reasonable expectation of success of removing infectious prion proteins from the plasma fraction of Brown using the method described by Gerba, where the Examiner has acknowledged previously that the bacterial endotoxin removed in Gerba is an entirely different unrelated molecule to the prions considered by Brown, it appears to be an unrealistic expectation. As noted, endotoxins are completely different molecules from prions which begs the question of why the ordinarily skilled artisan would consider, and even more so, expect, that the separation techniques of Gerba might be applicable to the removal of infectious prion proteins, especially when the nature and structure of infectious prion proteins was barely understood at the priority date of the present invention. The answer is simply that the ordinarily skilled artisan would **not** have a reasonable expectation of success of using the separation techniques of Gerba to remove infectious prion proteins.

At least based upon the foregoing, it would neither have been obvious to the person of ordinary skill to combine Brown with Gerba at least in view of the infinite number of possible options available nor would there have been a reasonable expectation of success. Accordingly, Applicant respectfully requests that the rejection of claims 1, 3, 6-10, 12, 13, 15,16, 25, 28 and 31-39 under 35 U.S.C. §103(a) be withdrawn.

III. New Claims

Applicant hereby submits new claims 40-64 for consideration. These claims are based upon the claims as filed originally and are fully supported by the specification. These new claims are further directed to aspects of the present invention such as what constitutes a blood plasma product, aspects of the blood plasma products and aspects of the depth filters. Applicant respectfully requests consideration and allowance of these new claims.

IV. Information Disclosure Statement

Applicant submits herewith a Request for Continued Examination (RCE) to permit consideration of the Information Disclosure Statement (IDS) and accompanying documents submitted herewith. The accompanying documents are those that have been submitted in Opposition Proceedings in the European Patent Office (EPO) for corresponding European Patent No. 1144015 (European Patent Application No. 00903788.8). A review of the documents associated with the Opposition Proceedings reveals that the European patent was maintained with amendment. Thus, patentable subject matter was recognized in view of a third-party post-examination/post-grant challenge.

V. Interview Request

Applicant appreciates the Examiner's continued attention to this application and willingness to communicate with the Applicant and the Applicant's legal representative. In the event this response does not result in the issuance of a Notice of Allowance or an indication of allowable subject matter, Applicant respectfully requests an interview with the Examiner and the Examiner's supervisor in an effort to identify allowable subject matter and expedite issuance of the same.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

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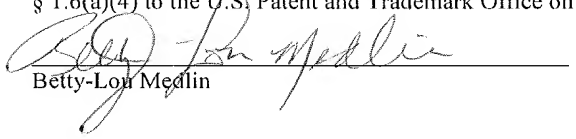

Betty-Lou Medlin